AMENDMENT(S) TO THE DRAWING(S)

Attached herewith are replacement sheets of drawings that include changes to Figures 2, 3, 4, 6, 8, 9 and 10. No new matter has been added.

Attachment: Replacement Sheets

REMARKS

I. Introduction

This paper is submitted in response to the Office Action mailed May 4, 2005 for the above-identified patent application. Claims 1-47 are pending in the application. Claims 20, 23-28 and 47 have been withdrawn from consideration. Claims 1-19, 21, 22 and 29-46 have been rejected.

The Examiner has made the Restriction Requirement mailed December 20, 2004 final and, therefore, claims 1-19, 21, 22 and 29-46 are now under consideration.

The Examiner has objected to the drawings because of the designation of multiple subsets for Figures 2-4, 6 and 8-10, *e.g.*, Figure 2' and Figure 2" should be relabeled as Figure 2A and Figure 2B. Applicants have relabeled the drawings and amended the Specification to overcome the objection to the drawings. No new matter has been added.

II. The Rejections Under 35 U.S.C. §112 ¶1 Should Be Withdrawn

The Examiner has rejected claims 1-10, 16, 19, 21, 22, 37 and 39 under 35 U.S.C. §112 ¶1, as failing to comply with the enablement requirement. The Examiner states that the present application is enabling for differentiating between cerebrospinal fluid or plasma from CJD+ and CJD-, plasma of BSE+ and BSE- cattle by measuring very specific molecular weight components of plasma and CSF. However, the Examiner alleges that the application does not reasonably provide enablement for a method of diagnosis of TSE or BSE utilizing any and all other body fluids nor utilizing any component having a molecular weight in the range of 1000-10,000.

Applicants have amended independent claims 1, 21 and 37 to recite that the polypeptide has a molecular weight in the range of from 1,010-31,800. It is respectfully submitted that such amendment is supported throughout the specification and, in particular, in the disclosed working examples. In addition, Applicants respectfully submit that the specification combined with knowledge of those skilled in the art fully supports utilizing body fluid taken from the subject. For example, proteins have been demonstrated in cerebrospinal fluid, blood and blood fractions, e.g., whole blood, serum, and plasma. In addition, it is commonly known in the art that many proteins found in the blood will also be found in urine, e.g., CK-MB in heart disease.

For at least these reasons, reconsideration and withdrawal of the rejection of claims 1-10, 16, 19, 21, 22, 37 and 39 under 35 U.S.C. §112 ¶1, as failing to comply with the enablement requirement, is respectfully requested.

III. The Rejections Under 35 U.S.C. §112 ¶2 Should Be Withdrawn

The Examiner has rejected claims 1-19, 21, 22 and 29-46 under 35 U.S.C. §112 ¶2, as indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner alleges that the claims appear to be only drawn to a method of diagnosis of TSE after determining whether the test amount is consistent with TSE. Thus, the Examiner alleges that the claims appear to be only drawn to a method of correlating a differential component amount with an already determined diagnosis of TSE.

Applicants have amended method claims 1, 21, 29, 32, 33, 35, 36, 37, 40 and 43, to clarify that the subject sample is compared to a reference amount representing no TSE

infection. For example, independent claim 1 has been amended to recite comparing the test amount of polypeptide in the sample to a reference amount of polypeptide, wherein the reference amount of polypeptide represents no TSE infection. It is respectfully submitted that one skilled in the art, with the benefit of the disclosure, would understand that the reference amount of polypeptide may be known in advance of testing the subject and determined, for example, from an individual without TSE, from a pool of individuals without TSE, or calculated from data of patients with and without TSE.

For at least these reasons, reconsideration and withdrawal of the rejection of claims 1-19, 21, 22 and 29-46 under 35 U.S.C. §112 ¶2, as failing to comply with the definiteness requirement, is respectfully requested.

The Examiner has rejected claims 1-19, 21, 22 and 29-46 under 35 U.S.C. 112, ¶2, as indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner alleges that since only molecular weight ranges are given, it is unclear whether all of the components differentially contained in the tested samples are polypeptides.

However, it is respectfully submitted that each of the independent claims clearly states that the molecular weights refer to the polypeptides. For example, claim 1 recites wherein the polypeptide is differentially contained in the body fluid of TSE-infected subjects and non-TSE-infected subjects, and has a molecular weight in the range of from 1,010-31,800. Independent claims 21, 29, 37 each contain similar recitations and, therefore, plainly relate the polypeptide differentially contained in the body fluid of TSE-infected subjects and non-TSE-infected subjects with the recited molecular weight range.

For at least these reasons, reconsideration and withdrawal of the rejection of claims 1-

19, 21, 22 and 29-46 under 35 U.S.C. §112 ¶2, as failing to comply with the definiteness requirement, is respectfully requested.

IV. Conclusion

In view of the foregoing remarks, reconsideration and allowance of pending claims 1-19, 21, 22 and 29-46 are respectfully requested.

Applicants believe that no additional fees are required in connection with this response. However, if additional fees are required, the Commissioner is hereby authorized to charge any additional payment, or credit any overpayment, to Deposit Account No. 01-2300, **referencing Docket Number 108140.00030.**

Respectfully submitted,

Rochelle K. Seide, Ph.D.
Registration No. 32,300
ARENT FOX PLLC
1675 Broadway
New York, NY 10019
Tel. No. (212) 484-3945
Fax No. (212) 484-3990
Customer No. 38485

FEE CALCULATION

Any additional fee required has been calculated as follows:

X If checked, "Small Entity" status is claimed.

	(Column 1)	(Column 2)	(Column 3)	SMALL ENTITY			LARGE ENTITY	
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADD'L FEE	OR	RATE	ADD'L FEE
TOTAL CLAIMS	47 MINUS	47	= -0-	x $25	$0.00		x $50	$
INDEP CLAIMS	17 MINUS	17	= -0-	x $100	$0.00		x $200	$
☐ FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				+ $180	$0.00	OR	+ $360	$
					$0.00			$

The U.S. Patent and Trademark Office is hereby authorized to charge and deficiency or credit any overpayment of fees associated with this communication to Deposit Account No. **01-2300** referencing docket number **108140.00030**.